

Consumer Medicine Information

Ibuprofen SR BNM

Ibuprofen

Modified release tablet 800 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Ibuprofen SR BNM.

This leaflet answers some common questions about Ibuprofen SR BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ibuprofen SR BNM against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Ibuprofen SR BNM is used for

Ibuprofen SR BNM contains ibuprofen. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

Ibuprofen SR BNM relieves pain and reduces inflammation (swelling or redness) that may occur:

- in different types of arthritis, a disease that mainly affect the joints with pain and swelling. These include rheumatoid arthritis, osteoarthritis and juvenile rheumatoid arthritis
- in menstrual cramps (period pain)
- in muscle and bone injuries such as sprains, strains, low back pain (lumbago), rheumatism and tendonitis such as tennis elbow
- from swelling and pain after setting broken or dislocated bones
- following surgery
- due to dental pain.

Ibuprofen SR BNM also relieves fever (high temperature).



Although Ibuprofen SR BNM can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

Ibuprofen SR BNM is only available with a doctor's prescription.

Ibuprofen SR BNM is not addictive.

Before you take Ibuprofen SR BNM

Ibuprofen SR BNM is not suitable for everyone.

When you must not take it

Do not take Ibuprofen SR BNM if you have:

- (or have previously) vomited blood or material that looks like coffee grounds
- (or have previously) bled from the rectum (back passage), have black sticky bowel motions (stools) or bloody diarrhoea
- a condition resulting in an increased tendency to bleed
- a peptic ulcer (i.e. stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
- or have a history of, ulcerative colitis or Crohn's disease
- severe heart failure
- severe liver failure
- severe kidney disease.

Do not take if you are in the last 3 months of pregnancy

Do not take Ibuprofen SR BNM if you have an allergy to:

- any medicine containing ibuprofen
- any of the ingredients listed at the end of this leaflet
- aspirin (also called acetylsalicylic acid) or any other NSAID medicine.

Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. Taking these medicines with Ibuprofen SR BNM may make the symptoms of allergy worse.

If you are not sure if you are taking any of these medicines, ask your pharmacist.

Do not take it after the expiry date ('Exp' (as per carton/bottle)) printed on the pack. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking lbuprofen SR BNM, talk to your doctor or pharmacist.



Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, including aspirin (also called acetylsalicylic acid) or other NSAID medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart disease or high blood pressure
- diabetes (the level of sugar in the blood is too high)
- heart failure
- swelling of ankles of feet
- heartburn, indigestion, stomach ulcer or any other stomach problems
- bowel or intestinal problems
- vomiting blood or bleeding from the rectum (back passage)
- severe skin reaction such as Stevens-Johnson syndrome
- chicken pox
- asthma, a disease where the lining of the lungs become inflamed (red and swollen), making it difficult to breathe or hay fever
- visual disturbances
- liver or kidney disease
- tendency to bleed or other blood problems.
- aseptic meningitis
- if you drink alcohol
- if you feel dehydrated
- if you are a current smoker.
- if you are in the first 6 months of pregnancy

Tell your doctor if you currently have an infection.

If you take Ibuprofen SR BNM while you have an infection, it may hide some of the signs and symptoms of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

Tell your doctor if you plan to have surgery.

Do not take this medicine if you are in your third trimester of pregnancy.

It may affect your developing baby if you take it during this time.

Do not breastfeed if you are taking this medicine.

Ibuprofen SR BNM is not recommended while you are breastfeeding.

Use with caution if you are over 65 years old.

Elderly persons are more sensitive to the effects of the medicine.

Do not give Ibuprofen SR BNM to a child aged under 12 years.

Safety and effectiveness in children younger than 12 years have not been established for this medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Ibuprofen SR BNM.



Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are taking Ibuprofen SR BNM.

Some medicines and Ibuprofen SR BNM may interfere with each other. These include:

- aspirin (also called acetylsalicylic acid), salicylates or other NSAID medicines
- warfarin or clopidogrel, medicines used to prevent/stop blood clots
- lithium, a medicine used to treat changes in mood and some types of depression
- SSRIs such as fluoxetine, medicines used to treat depression
- medicines used to treat high blood pressure or other heart conditions
- diuretics, also called fluid tablets
- methotrexate, a medicine used to treat arthritis and some types of cancer
- corticosteroids, such as prednisone, cortisone
- medicines used to treat heart failure or irregular heartbeats such as digoxin
- ciclosporin or tacrolimus, medicines used to treat certain problems with the immune system or to help prevent organ transplant rejection
- aminoglycosides, medicines used to treat certain infections
- gingko biloba, a herbal medicine used to improve memory
- quinolone antibiotics, medicines used to treat certain infections
- zidovudine, a medicine used to treat HIV
- cholestyramine, a medicine used to treat high cholesterol
- sulfonylureas, medicines to treat diabetes
- voriconazole or fluconazole, medicines to treat certain fungal infections.

The above medicines may be affected by Ibuprofen SR BNM, or may affect how well it works. You may need different amounts of Ibuprofen SR BNM, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **Ibuprofen SR BNM**.

How to take Ibuprofen SR BNM

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many Ibuprofen SR BNM tablets to take each day and when you should take them.



Adults

The usual dosage for Ibuprofen SR BNM is two tablets daily, taken as a single dose, preferably in the early evening.

Ibuprofen SR BNM is not recommended for children under 12 years.

Follow all directions given to you by your doctor carefully.

These directions may differ from the information contained in this leaflet.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Ibuprofen SR BNM may not work as well and your problem may not improve.

How to take it

Swallow Ibuprofen SR BNM whole with a full glass of water, with or straight after food.

This may help reduce the possibility of an upset stomach.

When to take it

Take it at about the same time(s) each day.

Taking it at the same time(s) each day will have the best effect. It will also help you to remember when to take it.

How long to take it

Do not take Ibuprofen SR BNM for longer than your doctor says.

Depending on your condition, you may need Ibuprofen SR BNM for a few days, a few weeks or for longer periods.

As with other NSAID medicines, if you are taking Ibuprofen SR BNM for arthritis, it will not cure your condition but it should help to control pain, swelling and stiffness.

It usually begins to work within a few hours but several weeks may pass before you feel the full effects of the medicine. If you have arthritis, Ibuprofen SR BNM should be taken every day for as long as your doctor prescribes.

For menstrual cramps (period pain), Ibuprofen SR BNM is usually taken at the first sign of pain or menstrual bleeding (whichever comes first). Treatment should be continued for a few days until the pain goes away.

If you are unsure whether you should stop taking Ibuprofen SR BNM, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.



Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking Ibuprofen SR BNM

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ibuprofen SR BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery. NSAID medicines can slow down blood clotting.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

If you get an infection while taking Ibuprofen SR BNM, tell your doctor.

Ibuprofen SR BNM may hide some of the signs of an infection and may make you think mistakenly, that you are better or that it is not serious. Signs of an infection may include fever, pain, swelling and redness.

Tell your doctor if, for any reason, you have not taking your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked.

See your doctor if you feel that your condition is not improving or is getting worse.. This will help your doctor to determine the best treatment for you.

Things you must not do

Do not take any other medicines to relieve pain and reduce inflammation while you are taking Ibuprofen SR BNM without first telling your doctor. These include:

aspirin (also called acetylsalicylic acid)



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- other medicines containing ibuprofen, the active ingredient in Ibuprofen SR BNM
- any other NSAID medicine.

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not take Ibuprofen SR BNM to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Ibuprofen SR BNM affects you.

It may cause dizziness, drowsiness, fatigue and visual disturbances in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed when you begin to take these tablets. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, certain side effects may be worse.

If you continue to feel unwell, tell your doctor.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (New Zealand – telephone 0800 POISON), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Ibuprofen SR BNM.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Ibuprofen SR BNM you may:

- feel sick or vomit
- have stomach pain
- have convulsions
- have a slow or fast heartbeat
- having ringing in your ears
- feel drowsy
- feel dizzy or even become unconscious.
- vomit blood or material that looks like coffee grounds



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 bleed from the rectum (back passage), black sticky bowel motions (stools) or bloody diarrhoea.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ibuprofen SR BNM.

Like all medicines, Ibuprofen SR BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea or vomiting
- loss of appetite
- heartburn or pain in the upper part of your stomach
- cramps, wind, constipation or diarrhoea
- headache
- sleepiness
- dizziness
- buzzing or ringing in the ears or other trouble hearing
- runny or stuffy nose
- sleeplessness (insomnia)
- feeling tired (fatigue).
- These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- changes in mood, for example depression, confusion, nervousness
- severe pain or tenderness in the stomach
- eye problems such as blurred vision, sore red eyes, itching
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of anaemia, such as tiredness, headaches, being short of breath, and looking pale
- yellowing of the skin and/or eyes, also called jaundice
- unusual weight gain, swelling of ankles or legs
- tingling of the hands and feet
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal.
- severe or persistent headache
- fast or irregular heartbeats, also called palpitations.

These may be serious side effects. You may need urgent medical attention.



Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- vomiting blood or material that looks like coffee grounds
- bleeding from the rectum (back passage), black sticky bowel motions (stools) or bloody diarrhoea
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson Syndrome)
- fever, generally feeling unwell, nausea, stomach ache, headache and stiff neck
- severe skin rash with fever
- pustules (boils and abscesses) on the skin.

Ibuprofen SR BNM may be associated with an increased risk of heart attack (myocardial infarction) or stroke.

Blood disorders and kidney problems may occur with Ibuprofen SR BNM. Ibuprofen SR BNM may be associated with chronic kidney disease in newborns (neonatal renal impairment).

Ibuprofen SR BNM may be associated with Oligohydramnios during pregnancy i.e., too little amniotic fluid, the fluid that surrounds the fetus in the abdomen, in the amniotic sac.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Ibuprofen SR BNM

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Ibuprofen SR BNM in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.



Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Ibuprofen SR BNM past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Ibuprofen SR BNM is available in blister packs of 30 tablets.

The tablets are white to off white coloured, pillow shaped film coated tablets plain on both sides.

Ingredients

Active ingredient:

ibuprofen

Inactive ingredients:

- xanthan gum
- hypromellose
- povidone
- purified water
- colloidal anhydrous silica
- stearic acid
- Opadry white 03A520003.

It does **not** contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor details

BNM Group 39 Anzac Road Browns Bay Auckland 0753

Ph: 0800 565 633



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